## REMARKS / ARGUMENTS

### 1. Response to March 19, 2009 Non-Final Office Action

For the convenience of the Examiner and clarity of purpose, Assignee has reprinted, for each of the three sections of the Office Action, the substance of the Office Action in ***10-point bolded and italicized font***. For each section, Assignee's arguments then follow in regular font.

> ***Claims 1-15, 19,20, and 24-28 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The use of "pump" in regards to the diastolic flow rate and mean flow rate is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See In re Mayhew, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The specification states on page 6, line 15 to page 7, line 16 that the "patient's diastolic VAD flow rate" is monitored and used to increase the pump speed and references the diastolic "pump" flow rate and mean "pump" flow rate and not just the use of "diastolic flow rate" or "mean flow rate" without the "pump"/VAD.***
>
> ***Claims 1-15, 19,20, and 24-28 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The subject matter not described in the original specification is the use of the "diastolic flow rate" and "mean flow rate" instead of the disclosure's description of the diastolic "pump" flow rate or mean "pump" flow rate. This new limitation of "diastolic flow rate" or "mean flow rate" represent a different range than what was originally presented.***

Assignee does not accede to the Office's characterization of the criticality of the word "pump" in reference to the claims, or what the specification would reasonably convey to one skilled in the art, and Assignee respectfully reserves its right to challenge those characterizations in the future. However, in an effort to advance prosecution, Assignee has reintroduced the word "pump" into the claims. Assignee expressly reserves the right to present the previously pending claims in the future.

> ***Claims 19 and 20 are rejected under 35 U.S.C. 1 12, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.***
>
> ***In claim 19, the claim is incomplete for omitting connection to the rest of the device of claim 7. The claim is just a listing of parts.***
>
> ***In claim 20, "may be use" is vague since it does not specifically state it is used to perform that function. If it may be used does it also mean that it may not be used for that function?***

Assignee does not accede to the Office's characterization of the claims and Assignee respectfully reserves its right to challenge those characterizations in the future. However, in an effort to advance prosecution, claims 19 and 20 have been amended. Assignee expressly reserves the right to present the previously pending claims in the future.

> ***Claims 1-15, 19, and 24-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Medvedev et a1 (2004/0152944). Medvedev discloses that the pump speed is changed based on or in response to the diastolic flow rate (e.g. paragraphs 57-61, DQ) and based on the heart rate or pressure (e.g. abstract). In addition, the pump speed is set in accordance with activities, such as sleep, normal activity, or high-energy activity, since the heart rate or other sensed parameters will change in response to these activities affecting the speed of the pump. For claim 19, the system senses pressure through the three feedback waveforms and for claim 8, the system of Medvedev includes an implantable flow measurement device since implantable device measures flow.***

As an initial matter, Assignee does not accede to the Office's characterization of Medvedev as applied to the claims and Assignee respectfully reserves its right to challenge that characterization in the future.

The Office may reject a claim as anticipated ***only*** when each and every claim limitation is described identically in the single prior art reference. *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997). "The test for anticipation is whether the claim reads on the product or process disclosed in the prior art, ***not on what that reference broadly teaches***." *SSIH Equip. S.A. v.*

*United States Int'l Traded Comm'n*, 718 F.2d 365, 218 USPQ 678 (Fed. Cir. 1983) (emphasis added). Further, the law of anticipation requires that the prior art reference disclose each claim limitation ***arranged in the order claimed***. See, e.g., *Brown v. 3M*, 265 F.3d 1349, 60 USPQ2d 1375 (Fed. Cir. 2001)("to anticipate, every element and limitation of the claimed invention must be found in a single prior art reference, arranged as in the claim"); *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 47 USPQ2d 1225 (Fed. Cir. 1998)("a finding of anticipation requires that the publication describe all of the elements of the claims, arranged as in the patented device."); *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990)("These elements must be arranged as in the claim under review."). The Office may not establish anticipation by mere "substantial similarity" between the prior art disclosure and the arrangement of claim limitations. See *Jamesbury Corp. v. Litton Indus. Prods., Inc.*, 756 F.2d 1556, 225 USPQ 253 (Fed. Cir. 1985).

Claims 1 and 26 each recite "***extracting*** the patient's diastolic pump flow rate from the pump flow rate", emphasis added. Claim 7 recites "the controller being programmed to ***extract a separate diastolic pump flow rate*** from the blood pump flow rate signal", emphasis added. For example, in paragraphs 33-36, the specification explains:

> [0033] FIG. 4 provides time plots of various physiologic parameters, including heart rate 201, peak systolic VAD flow rate 202, mean VAD flow rate 203, peak diastolic VAD flow rate 204, average peak to peak VAD flow (VAD flow maximum-VAD flow minimum) 205, and average pulsatility index 206. Each plot includes rest 210, exercise onset 212, and exercise conclusion 214 points for the patient. As shown in FIG. 4, the peak diastolic VAD flow plot 204 shows the greatest change in response to the onset and conclusion of exercise.
>
> [0034] Thus, in accordance with embodiments of the invention, the patient's diastolic VAD flow rate is monitored and the controller module 16 is programmed to increase the speed of the pump 12 in response to an increase in diastolic VAD flow, and decrease the pump speed in response to a decrease in diastolic VAD

> flow. In specific embodiments, the patient's peak diastolic VAD flow rate or average peak diastolic VAD flow rate is monitored and the pump speed is controlled in response thereto.
>
> [0035] FIG. 5 illustrates an analog flow processing system 250 in accordance with an exemplary embodiment of the invention. The system 250 accepts an analog voltage input signal 252 that is proportional to blood VAD flow rate and generates a digital output signal 254 to indicate when a patient has begun/finished exercising.
>
> [0036] The VAD flow signal 252 is ac coupled to a precision rectifier 256 to remove the mean VAD flow rate component from the analog VAD flow signal 252. The systolic VAD flow rate 260 and diastolic VAD flow rate 261 are extracted separately. The isolated systolic and diastolic VAD flow signals 260,261 are then low-pass filtered 262 to yield respective average peak values of the systolic and diastolic VAD flow rates. As noted herein, a patient's peak diastolic VAD flow rate or average peak diastolic VAD flow rate increases during exercise and decreases at rest. Thus, peak diastolic VAD flow rate or the average peak diastolic VAD flow rate is applied to a voltage comparator 264 to compare the signal to a predetermined threshold 266 and provide the binary indication 254 of when the patient is exercising. The pump speed may then be adjusted accordingly.

Thus, as described in the specification and presently claimed, the diastolic flow rate is extracted separately, such as by use of the system shown in FIG. 5 to produce the separate time plot of FIG. 4.

In contrast, while Medvedev does discuss a diastolic flow rate, nowhere does he actually teach "***extracting*** the patient's diastolic pump flow rate from the pump flow rate", emphasis added, as claimed in claims 1 and 26, much less "the controller being programmed to ***extract a separate diastolic pump flow rate*** from the blood pump flow rate signal", emphasis added, as claimed in claim 7.

Rather, Medvedev's one and only use of the word "diastole", or any variant thereof, is found in his paragraph 59, reproduced below:

> [0059] where $Q_{peak(-)}$ is the average of the peak minimum instantaneous flow rates within each cardiac cycle recorded over a given control cycle. This peak minimum flow is associated with ventricular diastole when the pressure across the pump is maximum.

Thus, Medvedev is only concerned with minimum peaks, which he associates with ventricular diastole, rather than an actual ***extracted diastolic flow rate***. More specifically, Medvedev appears to merely teach monitoring a composite flow signal derived from a power calculation, as with previous prior art references made of record, averaging the minimum peaks, and using that average of the minimum peaks in his invention. Nowhere does Medvedev, or any of the previous prior art references made of record, actually teach "***extracting*** the patient's diastolic pump flow rate from the pump flow rate", emphasis added, as claimed in claims 1 and 26, much less "the controller being programmed to ***extract a separate diastolic pump flow rate*** from the blood pump flow rate signal", emphasis added, as claimed in claim 7.

Furthermore, many of the limitations of the claims are not addressed at all in the Office Action. For example, claims 3 and 6 each recite "wherein changing the predetermined speed includes increasing the pump speed in response to an increase in the diastolic pump flow rate." Claim 4 recites "wherein changing the predetermined speed includes increasing the pump speed in response to an increase in the heart rate." Claim 10 recites "wherein the controller is programmed to increase the speed of the pump in response to an increase in the separate diastolic pump flow rate." Claim 12 recites "wherein the controller is programmed to increase the speed of the pump in response to an increase in at least one of the separate diastolic pump flow rate or the heart rate." Claim 27 recites "increasing the speed of the pump in response to an increase in

the extracted diastolic pump flow rate."

No mention of these limitations is made in the Office Action. Assignee can find no mention of these limitations in Medvedev. For example, Assignee can find no discussion in Medvedev of increasing the pump speed in response to either an increase in diastolic flow rate or an increase in heart rate.

Finally, Medvedev actually teaches away from some pending claim limitations. For example, claim 8 recites "further comprising an implantable flow measurement device having an output for providing the flow rate signal." Claim 19 recites "further comprising an implantable pressure sensor for providing pressure sensor data to the controller."

"A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." In re Gurley, 27 F.3d 551, 553 (Fed. Cir. 1994); see KSR, 127 S. Ct. at 1739–40 (explaining that when the prior art teaches away from a combination, that combination is more likely to be nonobvious).

In the present case, Medvedev certainly discourages the use of the claimed sensors. For example, as stated in paragraph 25, Medvedev "proposes … using no pressure or ECG type sensors (so-called "sensorless" approach)." In paragraph 80, Medvedev again states that he prefers to use "no pressure or flow sensors". Medvedev advocates his approach, because other systems "require extra hardware inside the patient and increase the risk of complication." For example, in paragraph 65, Medvedev states that deriving suction based on intrinsic pump signals "removes the technical and reliability problems associated with direct flow, pressure and heart

rate sensing". Thus, Medvedev's goal is to provide a system with no extra hardware inside the patient in an effort to decrease the risk of complication. As a result, because Medvedev repeatedly discourages the use of the claimed sensors, Medvedev explicitly teaches away from a system including the claimed flow and/or pressure sensors.

This is an important distinction because algorithms which utilize intrinsic pump signals to detect suction, such as Medvedev's, are inherently dependent on the pump's ability to react to changes in load. Therefore they are intrinsically slower in responding to short duration events (e.g. imminence of suction) due to the angular momentum (gyroscopic effect) of the rotor impeller. Suction detection algorithms implemented with intrinsic pump signals (e.g. current and speed) derived from pumps with more massive rotors or with rotors which spin faster will be slower in response than algorithms based on independent measurements (e.g. blood flow rate).

Additionally, due to non-linearities in a pump's flow versus differential pressure versus current versus speed characteristics, current and power alone ***cannot*** adequately indicate suction. Pumps systems which may have bearing wear, mechanical failures, thrombos, etc. will assuredly cause a flow derivation algorithm based on power and speed to yield erroneous results. Erroneously elevated power levels would be the most likely result and will simply convince the algorithm that the pump is operating somewhere else on it's characteristic/performance curve. Clinically, in this event, the control system would most likely ***lower*** the pump speed to keep the calculated flow rate constant which could yield a physiologically lower flow than desired perhaps placing the patient at risk.

The present invention's inclusion of the flow meter and/or pressure sensor, against the

teaching of Medvedev, may provide a true, and possibly even calibrated, metric of blood flow with a sufficiently high bandwidth to capture subtle changes in blood flow rate. Furthermore, patients in the immediate post-operative phase, or those with significantly compromised ventricular function, may not generate adequate, if any, flow waveform pulsatility. In this case Medvedev's algorithmic approach may falsely detect suction and drive pump speed down to the point where the patient is not adequately supported and injured. Thus, the present invention provides a distinct advance over, which is explicitly taught away from by, the prior art.

For at least these reasons, Assignee respectfully submits that the presently pending claims are patentable over the disclosure and teaching of the prior art made of record. Reconsideration and withdrawal of this rejection is requested.

## 2. Retraction of Previous Arguments

In light of *Hakim v. Canon Avent Group PLC*, 479 F.3d 313, 81 U.S.P.Q.2d (BNA) 1900 (Fed. Cir. 2007), Assignee retracts and expressly disavows all arguments made in all related pending and expired applications.

Furthermore, in light of the mootness of the previous rejections, Assignee hereby expressly retracts its previous arguments with respect to the previously presented claims in accordance with *Hakim v. Canon Avent Group PLC*, 479 F.3d 313, 81 U.S.P.Q.2d (BNA) 1900 (Fed. Cir. 2007). Specifically, the previous arguments were based on previously pending claims. Because the Examiner has refused to accept the previous arguments, and has instead required claim amendments, the basis for those arguments has necessarily changed. Therefore, precisely

because the previous arguments were made with respect to previously pending claims, which have been amended, Assignee hereby expressly retracts those arguments.

## 3. CONCLUSION

Claims 1-15, 19, 20, and 24-28 are pending in this application. Assignee submits that each claim is patentable. A notice of allowance is respectfully requested.

The Commissioner is authorized to charge to deposit account 121322/0021906.023US any other fees necessary to make this and related papers, if any, timely and effective.

Assignee thanks the Examiner for her consideration and effort on this file. If there are any questions or if additional information is needed, the Examiner is invited to telephone or email the undersigned.

Respectfully submitted,

**LOCKE LORD BISSELL & LIDDELL LLP**

By /David L. Terrell/
David L. Terrell
Reg. No. 50,576
Tel.: (713) 226-1495
dterrell@lockelord.com